

CLAIMS

What is claimed is:

1. A hydrophilic inclusion complex, comprising:
 nano-sized water-insoluble lipophilic particles;
 an amphiphilic polymer which surrounds said nano-sized lipophilic particles to form said inclusion complex, wherein said amphiphilic polymer renders said inclusion complex hydrophilic in water and bioavailable in the human body.
2. The hydrophilic inclusion complex as recited in claim 1, wherein said lipophilic particles comprise organic materials selected from the group consisting of pharmaceutical compounds, food additives, cosmetics, agricultural products and pet foods.
3. The hydrophilic inclusion complex as recited in claim 2, wherein said lipophil particles are selected from the group consisting of: peptides and polypeptides, nucleotides and co-ferments, vitamins, steroids, porphyrins, metal-complexes, purines, pyrimidines, antibiotics and hormones
4. The hydrophilic inclusion complex as recited in claim 2, wherein said lipophilic particles are pharmaceutical compounds.
5. The hydrophilic inclusion complex as recited in claim 1, wherein said nano-sized hydrophilic lipophilic particles interact with said amphiphilic polymer via the formation of non-valent bonds.
6. The hydrophilic inclusion complex as recited in claim 1, wherein said amphiphilic polymer and said lipophilic particles form a polymer complex having a hydrophilic-lipophilic balance that renders said polymer complex soluble in water.

7. The hydrophilic inclusion complex as recited in claim 1, wherein said nano-sized insoluble lipophilic particles are in the range of from 10-100 nanometers in size.

8. A method for forming a hydrophilic inclusion complex, the method comprising the steps of:

- a. preparing a polymer solvent comprising amphiphilic polymer molecules in an aqueous solvent;
- b. preparing a carrier solvent comprising lipophilic compounds in a non-aqueous solution;
- c. adding said carrier solution to said polymer solution to form a emulsion;
- d. dispersing said lipophilic compounds in said emulsion by adding said emulsion to a turbulent zone in said polymer solution wherein said lipophilic compounds form nano-sized lipophil particles in a nano-emulsion;
- e. removing said carrier solvent from said nano-emulsion, wherein said polymer molecules surround said nano-sized lipophil particles to form said hydrophilic inclusion complex.

9. The method as recited in claim 8, wherein said polymer solution in said preparing step is contained in a first vessel of a chemical reactor and said lipophil solution is contained in a second vessel of a chemical reactor.

10. The method as recited in claim 9, wherein said dispersing step occurs within a turbulent flow in the polymer solution within said chemical reactor.

11. The method as recited in claim 8, wherein said lipophil solution is comprised of lipophilic compounds selected from the group consisting of: peptides and polypeptides, nucleotides and co-ferments, vitamins, steroids, porphyrins, metal-complexes, purines, pyrimidines, antibiotics and hormones.

12. The method as recited in claim 8, wherein said lipophilic compounds are insoluble in water.

13. The method as recited in claim 8, wherein said polymer is an amphiphilic polymer.

14. The method as recited in claim 8, wherein said amphiphilic polymer is selected from the group consisting of: natural polysaccharides, polyacrylic acid and its derivatives, polyethylene imine and its derivatives, polymethacrylic acid and its derivatives, polyethylene oxide and its derivatives, polyvinyl alcohol and its derivatives, polyacetylene derivatives, polyisoprene derivatives and polybutadiene derivatives.

15. The method as recited in claim 8, wherein said removing step further comprises the step of evaporating said carrier solvent via vacuum distillation.

16. The method as recited in claim 8, wherein said emulsion in said adding step has a Reynolds number of not less than 10,000.

17. The method as recited in claim 8, further comprising the step of heating said mixture of polymer solution with carrier to provide carrier's steam which condenses and dissolves said lipophilic compounds to form said lipophilic solution.

18. The method as recited in claim 17, wherein said polymer solution is heated to a temperature above the boiling point of the carrier solution but lower than the boiling point of the polymer solution.

19. A chemical reactor for forming an emulsion used in the preparation of an inclusion complex, comprising:

a first vessel for containing a polymer solution;

a second vessel for containing lipophilic compounds and non-aqueous solvent of lipophilic compounds; and

a dispersing apparatus for dispersing said solution of lipophilic compounds in a carrier within said polymer solution, said dispersing apparatus being positioned within said first vessel and which creates a vigorous turbulent flow within said polymer solution, said first and second vessels being connected to each other to permit continuous circulation of the carrier and wherein said lipophil migrates from said second vessel to said first vessel.

20. The chemical reactor as recited in claim 19, wherein said dispersing apparatus disperses said lipophilic compounds in said lipophilic solution into nano-sized particles.

21. The chemical reactor as recited in claim 20, wherein said dispersing apparatus is a nano-disperser.

22. The chemical reactor as recited in claim 19, wherein said dispersing apparatus operates in said first vessel at a rate of approximately 5,000-10,000 revolutions per minute.

23. The chemical reactor as recited in claim 19, further comprising a screen positioned above said polymer solution in said first vessel to prevent said turbulent flow from entering an air space which forms above said polymer solution in said first vessel.

24. The chemical reactor as recited in claim 19, further comprising a first heating apparatus for heating said polymer solution in said first vessel.

25. The chemical reactor as recited in claim 19, further comprising a mixing apparatus positioned below said second vessel for mixing said lipophilic solution in said second vessel.

26. The chemical reactor as recited in claim 19, further comprising a first condenser connected to a vacuum pump, said vacuum pump extending into said first vessel.

27. The chemical reactor as recited in claim 19, further comprising a second condenser connected to second vessel.

28. The chemical reactor as recited in claim 19, wherein said polymer solution in said first vessel is in fluid communication with said lipophilic solution in said second vessel via a tube connected between said first vessel and said second vessel.

29. The chemical reactor as recited in claim 28, wherein said lipophilic solution is added to said polymer solution in said first vessel via said tube connected between said first vessel and said second vessel, said tube having an exit end extending within said polymer solution in said first vessel, wherein said lipophil solution which flows through said exit end of said tube enters said first vessel in said region of vigorous turbulent flow.

30. The chemical reactor as recited in claim 29, wherein said first vessel comprises an air space above said polymer solution.

31. The chemical reactor as recited in claim 30, wherein said first vessel further comprises a screen positioned therein above said polymer solution to prevent said turbulent flow from entering said air space above said polymer solution.

32. The chemical reactor as recited in claim 19, further comprising a pump for circulating said lipophil solution and said polymer solution between said first vessel and said second vessel.

33. A process for forming a nano-emulsion for the preparation of a water soluble inclusion complex, the process comprising the steps of:

a. preparing an emulsion comprising solution of amphiphilic polymer molecules in an aqueous solvent and a solution of lipophilic compounds in a non-aqueous solvent carrier;

b. dispersing said lipophilic compound within said emulsion, wherein said lipophilic compound forms nano-sized particles, said nano-sized particles forming a nano-emulsion; and

c. removing said carrier solvent from said nano-emulsion, wherein said polymer molecules surround said lipophilic particles to provide said water soluble inclusion complex.

34. The process as recited in claim 33, wherein prior to the dispersing step, the process further comprises the step of heating the emulsion to a temperature lower than the boiling point of the emulsion, and above the boiling point of the carrier solvent.

35. The process as recited in claim 33, wherein said preparing, dispersing and removing steps occur in a chemical reactor.

36. The process are recited in claim 34, wherein said dispersing step occurs within a turbulent flow in the polymer solution within said chemical reactor.

37. The process as recited in claim 33, wherein said lipophilic compound is selected from the group consisting of: organic materials selected from the group consisting of drugs, food additives, cosmetics, agricultural products and pet foods.

38. The process as recited in claim 33, wherein the polymer in said polymer solution is selected from the group consisting of: natural polysaccharides, polyacrylic acid and its derivatives, polyethylene imine and its derivatives, polymethacrylic acid and its

derivatives, polyethylene oxide and its derivatives, polyvinyl alcohol and its derivatives, polyacetylene derivatives, polyisoprene derivatives and polybutadiene derivatives.

39. The process as recited in claim 33, wherein prior to the preparing step, the process comprises the step of determining and calculating the characteristics and properties of said polymer molecule and said lipophilic compound to be used in the formation of said inclusion complex.

40. The process as recited in claim 38, wherein said polymer is selected based upon the molecular weight, dimensions and solubility in non-aqueous solvents of the lipophilic compound to be used in the formation of said inclusion complex.

41. The process as recited in claim 33, wherein said polymer is selected via an algorithm which considers one or more of the following characteristics of the polymer : molecular weight, basic polymer chain length, length of kinetic unit, solubility in water, degree of solubility, degree of polymeric chain flexibility, integral hydrophilic-lipophilic balance, and polarity of hydrophilic groups.

42. The process as recited in claim 36, wherein said emulsion which enters the turbulent flow in said dispersing step has a Reynolds number of not less than 10,000.

43. A method for forming a water-soluble inclusion complex in a chemical reactor, the method comprising the steps of:

- a. preparing an emulsion in a first vessel of said chemical reactor, said emulsion comprising a carrier solvent and an amphiphilic polymer solution;
- b. adding an lipophilic compound to a second vessel of said chemical reactor;
- c. heating said emulsion wherein vapor from said emulsion condenses in said second vessel and dissolves said lipophil to form a lipophilic solution;

096647-09204
T03250-2499660

d. adding said lipophilic solution to said emulsion in said first vessel, said lipophil solution being added to said first vessel in the vicinity of a disperser apparatus positioned in said first vessel;

e. dispersing said lipophilic solution wherein said lipophilic compounds form nano-sized lipophil particles in a nano-emulsion;

f. removing said carrier solvent from said nano-emulsion wherein said amphiphilic polymer surround said nano-sized lipophil particles to provide said water-soluble inclusion complex.

44. The method as recited in claim 43, wherein said dispersing step occurs within a turbulent flow in the polymer solution within said first vessel.

45. The method as recited in claim 43, wherein said lipophil solution is comprised of lipophilic compounds selected from the group consisting of: peptides and polypeptides, nucleotides and co-ferments, vitamins, steroids, porphyrins, metal-complexes, purines, pyrimidines, antibiotics and hormones.

46. The method as recited in claim 43, wherein said amphiphilic polymer is selected from the group consisting of: natural polysaccharides, polyacrylic acid and its derivatives, polyethylene imine and its derivatives, polymethacrylic acid and its derivatives, polyethylene oxide and its derivatives, polyvinyl alcohol and its derivatives, polyacetylene derivatives, polyisoprene derivatives and polybutadiene derivatives.

47. The method as recited in claim 43, wherein said removing step further comprises the step of evaporating said carrier solvent via vacuum distillation.

48. The method as recited in claim 43, wherein said emulsion added to said polymer solution in said adding step has a Reynolds number of not less than 10,000.

49. The method as recited in claim 43, wherein said polymer solution is heated to a temperature above the boiling point of the carrier solvent but lower than the boiling point of the polymer solution.